April 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Performance Standard for Vibrio Vulnificus; Request for Comments
Docket No. 98P-0504
64 Fed. Reg. 3300 (January 21, 1999)

AARP appreciates this opportunity to comment on a petition filed by the Center for Science in the Public Interest (CSPI), and related questions, relating to *Vibrio vulnificus*. Older persons are among the subpopulations most at risk from food-borne illness, and *V. vulnificus* is one of the most lethal pathogens: there is evidence that exposure to even very low levels of the pathogen can lead to death or serious illness. In addition to relatively healthy older persons, a significant proportion of whom are at risk because of low gastric acidity, those young and old who suffer from diabetes mellitus, liver disease, leukemia, hepatitis, AIDS and alcoholism, among other conditions, are particularly susceptible to *V. vulnificus*. Also included in this group are persons who have received organ transplants and those taking systematic corticosteroids for asthma and arthritis.[1]

Since 1989, *V. vulnificus* has killed over 100 people and has sickened many more. The annual death toll has reached as high as 24 (in 1996), and last year, another 18 victims died as a result of eating raw shellfish containing this pathogen. AARP agrees with CSPI that FDA should take decisive action by establishing a performance standard for raw molluscan shellfish from waters associated with past *V. vulnificus* infections. The performance standard should require that shellfish processors reduce the pathogen to nondetectable levels in molluscan shellfish intended for raw consumption. With the availability of new post-harvest treatment technologies that are capable of reducing *V. vulnificus* contamination in raw shellfish to nondetectable levels, FDA can act to protect consumers from unnecessary health risks by requiring that the industry produce a significantly safer product.

[1] Douglas L. Park, Ph.D. & Yupin Chen, Ph.D., *Pathogen Reduction for Vibrio Species in Shellstock Oysters: An Overview and Commentary* 3 (unpublished).

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601 E Street, NW Washington, DC 20049 (202) 434-2277 www.aarp.org
Joseph S. Perkins *President* Horace B. Deets *Executive Director*

Current measures to fight *V. vulnificus* have been ineffective.

The regulatory response, to date, has been ineffective. There is no evidence to suggest that the refrigeration controls, consumer education efforts, and warning label requirements adopted over the past few years by the harvesting states, in conjunction with the Interstate Shellfish Sanitation Conference (ISSC), have done anything to reduce the death and illness toll from contaminated shellfish. In particular, the warning label requirement adopted by the ISSC does not even ensure that the warning will reach consumers, but instead requires warning labels to be affixed to bags of shellfish in wholesale shipments *to retailers*.

Moreover, FDA's seafood HACCP program has not eliminated, or even reduced, *V. vulnificus* contamination of shellfish. FDA had predicted that HACCP would avert anywhere from 12 to 30 annual cases of *V. vulnificus* infection within three years. To date, since December 1997, when the seafood HACCP rule became effective, there has been no documented decrease in the pathogen's annual death and illness toll. The HACCP approach has not been effective against *V. vulnificus* because mandated pathogen-control techniques, such as refrigeration controls and tagging requirements, are simply inadequate by themselves. While tagging does help prevent processors from purchasing shellfish from harvesting beds that are closed due to sewage or other contamination, it fails to prevent processors from purchasing legally-harvested contaminated shellfish from beds that remain open despite their high concentrations of *V. vulnificus*.

The seafood HACCP rule could be an effective food-safety program for raw shellfish if it were combined with a pathogen-reduction performance standard. Such a strategy has been successful in the meat and poultry industry, where the *Salmonella* performance standard imposed by the United States Department of Agriculture in conjunction with the meat and poultry HACCP program has apparently yielded an impressive decrease in *Salmonella* contamination of chicken, beef, and swine carcasses.

FDA should adopt a performance standard for raw shellfish that requires nondetectable levels of *V. vulnificus*.

To adequately protect consumers of raw shellfish, the performance standard must require nondetectable levels of the pathogen. The infectious dose for *V. vulnificus* is not known, but there is evidence that exposure to even very low levels of the pathogen can lead to death or serious illness. For instance, at least one person has died after eating a single contaminated raw oyster, and data from 1994 indicate that oysters containing less than 300 *Vibrio vulnificus* organisms per gram of oyster meat at harvest can be deadly. Consequently, no scientific basis exists for setting a performance standard above nondetectability. A standard that would permit raw shellfish containing any detectable level of *V. vulnificus* organisms to leave processing plants would have to be viewed as arbitrary.

Another consideration favoring adoption of a performance standard requiring nondetectable levels of *V. vulnificus* is temperature control. Improper temperature control of post-processed raw shellfish can increase pathogen concentration to dangerous levels by the time the product reaches consumers. The organism's ability to proliferate rapidly even at room temperature means that raw shellfish that initially contained low concentrations of *V. vulnificus* could ultimately pose a grave risk to consumers, especially those in the high-risk groups.

The benefits of post-harvest treatment of raw shellfish to eliminate *V. vulnificus* outweigh the costs.

FDA has estimated the annual cost of *V. vulnificus*-related deaths and illnesses at approximately $120 million. The annual cost is high in part because survivors of *V. vulnificus* infection can face debilitating injury, sometimes requiring amputation and long-term rehabilitation.

Requiring the industry to achieve nondetectable levels of the pathogen in their products could substantially reduce or eliminate these health costs. These annual savings would come at a modest price, according to one company that developed a post-harvest treatment process using mild heat pasteurization. John Schegan of Ameripure Oyster estimates that his company's pasteurization methodology would only increase product price by approximately 8 cents per oyster. We believe that many consumers would be willing to pay a slight increase in price for shellfish, provided the necessary post-harvest treatments result in a significantly safer product.

There is technology available today that would significantly reduce, if not eliminate, the health risk posed by raw molluscan shellfish. FDA should do everything in its power to encourage, if not require, that it be used. Toward this end, AARP believes that the agency should establish a performance standard that requires nondetectable levels of *V. vulnificus*. Action in this single area would have an immediate and profound impact on a deadly pathogen.

If you have any further questions, please contact Larry White of our Federal Affairs Staff at (202) 434-3800.

Sincerely,

Martin A. Corry
Director
Federal Affairs